ARTEC

Anesthesia system

Operating instruction

CE 0482

Version 1.2. Status 04.10/

Picture shows Artec with optional components

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1 General Information

The Medical Equipment Regulations (MedGV), and the law on technical medical working materials (MPBetreibV) stipulate that the attention of the operator must be drawn to the following:

The operation of the Unit must be carried out only by qualified personnel. Exact knowledge and understanding of the Operating Instructions is a pre-conditioned for operation.
Use of the equipment is solely for that as stipulated in the Operating Instructions.
Inspections and servicing must be duly entered in the Logbook of the Unit. The Equipment must be inspected at regular intervals by qualified personnel only.
F.Stephan GmbH stipulates a half-yearly inspection and maintenance by one of its authorized Service Technicians.
Before each use of the unit, a complete function test of the unit must be carried out.
In the case on medico.technical devices with electrical connection, the standards of particular VDE 0751 and IEC 601 must be closely complied with. According to these standards, such devices may only be set up and put into operation by the manufacturer or his expressedly authorized technician or dealership.
Unit equipped with a pressure reducer should undergo a basic overhaul at least every 5 years for reasons of safety.
An emergency ventilation system (e.g. Ambu-Bag) must always be in close proximity of the unit.
F. Stephan shall assume no responsibility or liability for any damage or defects arising from non-observance of the above-mentioned information.

2 Technical Description

Driven by customer requests and requirements, the ARTEC model series had been designed and developed as a compact universal version. At the same time high quality-standards and maximum economy has been achieved.
The elementary structure ensures a good overview and quick allocation and adjustment of parameters for the respective unit components. The ARTEC anesthesia unit is an inhalation anesthesia unit that is equipped with a anesthesia agent specific vaporizer for use in a semi-closed system
The unit consists of a basic housing of stainless steel in which a drawer is provided.
Located above that is the gas-mix unit (GME, with which the available medical gases O_2, N_2O and (optional) compressed air can be dosaged.
The GME consists of an integrated pneumatic unit with relvant safety valves providing for N_20 block and O_2 deficiency signal and the dosage unit for the above-mentioned medical gases.
On the right-hand side, an anesthesia agent specific vaporizer can be mounted on special mounting racks (one or two-fold).
Located on the basic unit and depending on model, there is provided a stainless steel shelf for additional monitoring or a ventilation module with integrated monitoring.
On the reverse side of the unit there are standard connections for gas supply linea and depending on model, holding racks for reserve bottles with integrated high-pressure reducers.
The unit is also equipped with four plug sockets for electrical power supply for additional monitors. These sockets are constantly supplied with current regardless of the Ventilators ON/OFF power supply status.

2.1 Possible Expansion and Upgrading of the Unit

Basic Model

The ARTEC basic model is suitable for wall mounting. For such mounting, the mounting rails of the basic unit ar attached to the V_2A rails.
For wall mounting, exact vertical mounting of the unit must be strictly observed, otherwise inexact mounting could lead to falsh measuring results of gas flows. An adjustable distancer device provides a precise alignment of the unit.

Unit Model with Mobile Stand

The unit can be mounted on a mobile stand that enables and ensures variable site operation.

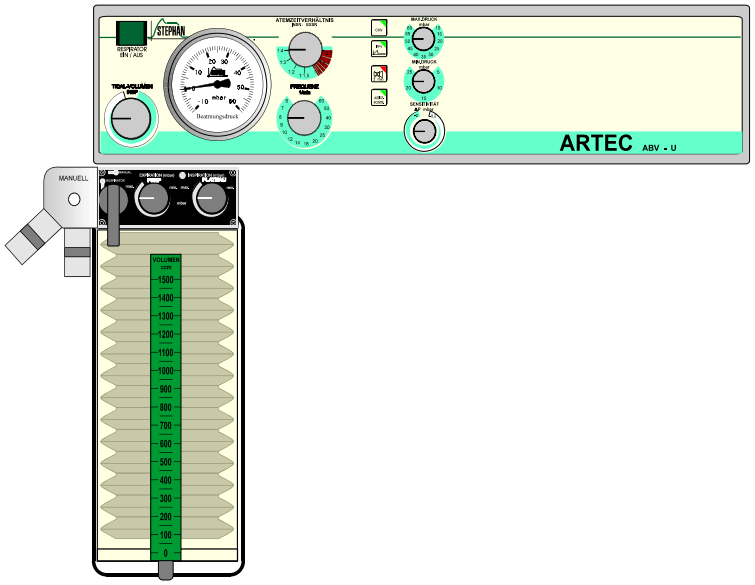
The basic unit can be mounted on the mobile stand profile (80x30) by tightening the four mounting bolts. The mobile stand can be equipped with a stand-alone oxygen, compressed air and vacuum generator module „STAXEL“

Gas Supply:

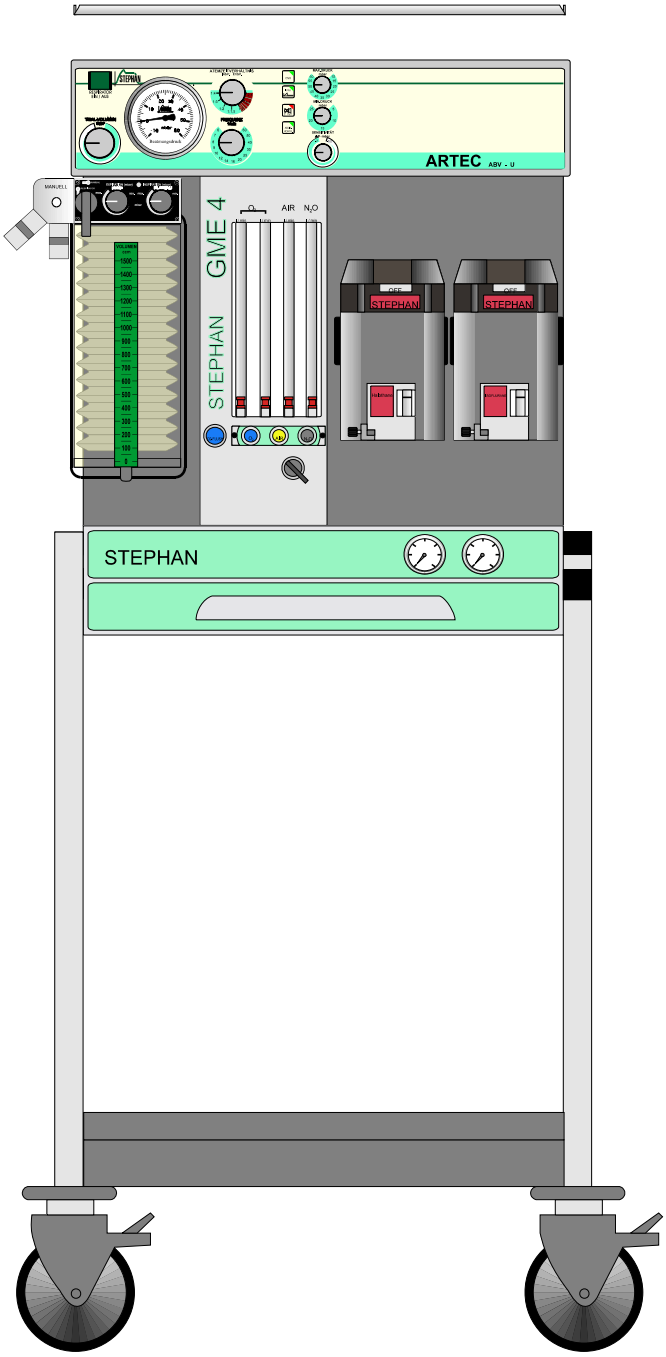
The unit is designed with a central gas supply coupling connection. A set of hoses is supplied with the unit for the three types of gases O_2, N_2O and compressed air (if air is provided).
Gas supply can either be via a central gas supply network, or via bottle supply with 10 litre bottles O_2 and N_2O. To ensure uninterrupted gas supply, in the event of breakdown of the central gas supply, 2 litre reserve bottles can be connected.

An alternative to bottled gas supply, the ARTEC anesthesia unit offers the possiblity of a decentalized oxygen supply via the supply „outlet“. This is the „STAXEL“ that has been especially developed as an oxygen / compressed air and vacuum generator.

Ventilation Module:



The ventilation module ABVA is easy to use and can eventually mounted to the basic unit later on. For this the V_2A shelf is removed from the basic unit. After that the ventilation module can be mounted to the basic unit via two mounting bolts. The compressed air supply of the ventilator is created via a connection line to the basic unit.



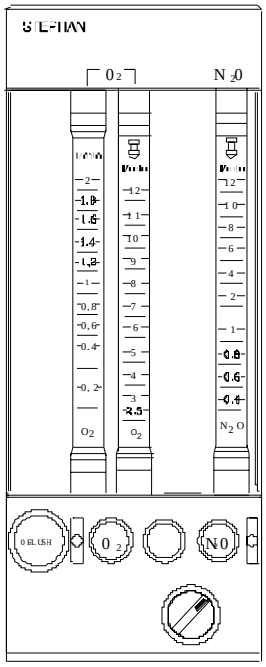
After attaching the V_2A shelf, you now have a respiratory-contolled anesthesia ventilation system with the current necessary state-of-the-art monitoring system.
It is strongly advised to have the installation carried out by our specially trained Stephan Service Team.

2.2 Scope of Use and Application

The ARTEC is an inhalation anesthesia unit for the manual anesthesia of infants, children and adults.
It can be used in conjunction with a ISO circuit system, but can also be operated with open ventilation systems. The scope of applications of the ARTEC anesthesia unit ranges from use in the practitioner’s surgery to hospital operation theatres.

3 Description

3.1 Gasmixing unit 3 and 4

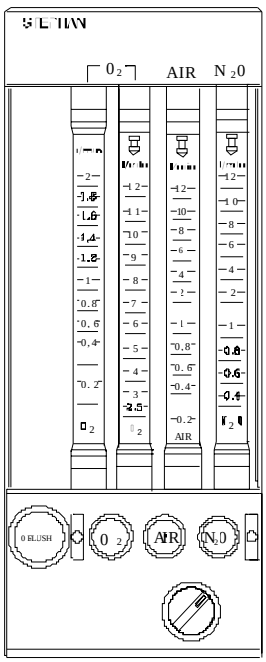


Gasmischeinheit GME 3
Art.Nr. 150 61 070

The gasmixing unit serves as a dosage unit for medical gases (e.g. O_2, N_2O, Air). The choosen gases can mixed in a arbitary relation, but the ratio-system guarantees a O_2-concentration not lower then 21 % (see below). The different gases are clearly displayed with rotary buttons.

To avoid mistakes, the O_2-rotary button discerns from the others.
A unintentional move is prevented by a protection.
The dosing device makes a continuous flow enable, when opening the valves by rotation against clockwise.

The O_2-measuring range contains two measuring devices. This makes a fine dosage possible.
The left measuring tube has a range from 0 to 2 l/min O_2, the right tube has a range from 2 to 15 l/min O_2. As point of observation serves the upper surface of the floating body.



Gasmischeinheit GME 4
Art.Nr. 150 61 071

The measuring tubes for AIR and/or N_2O are laid out as double cone measuring tubes. The lower zone of the measuring tubes (AIR/N2O) is more finely gradated than the upper.
The side parts of the GMUE 3/4 can be changed in their dimensions so it is possible to use different types of measuring tubes (e.g. firm Rota, firm KDG and others).

3.2 O_2 – Ratiosystem (optional)

The Gasmixing units GME 3 and GME 4 can be equipped optionally with a pneumatical system to assure at every flowrange of N_2O a minimum concentration of oxygen of 25 % O_2 (+/- 5%).
The so called O_2 - Ratiosystem avoids the delivery of pure N_2O to the breathing system.

Mode of operation

The O_2 – Ratiosystem examines the O_2 – Flowrate. If there is no O_2 – Flow the N_2O – Line is blocked. Thus it is impossible to apply pure N_2O to the breathing system without opening the O_2 – Valve at the GME. Only when the O_2 – Valve is opened counterclockwise, a N_2O – flow according the flowrate of O_2 can be adjusted. The minimal achievable oxygen concentration is 25 % +/- 5%.

Control of function

1. Close O_2 – and N_2O – Valve at the GME.
2. Open N_2O – Valve to maximum There should be no N_2O – Flow
3. Open O_2 – Valve counterclockwise N_2O – Flow is increasing

For example:

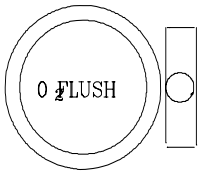
Adjust 1 l/min O_2 N_2O – Flow should be 3 l/min +/- 0,2 l/min
Adjust 3 l/min O_2 N_2O – Flow should be 9 l/min +/- 0,6 l/min

Caution

The O_2 – Ratiosystem controls the O_2 – concentration in the freshgas. It doesent prevent in any case a hypoxic gasmixture in the circlesystem.

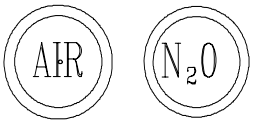
Caution

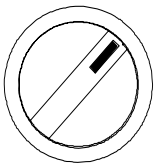
Please do control the inspiratory O_2 – concentration by using an oxygenmonitor.



3.3 O_2-Flush

By pressing the O_2 Flush push-button, a fast oxygen supply (approx. 50 litres per minute) is activated directly to the fresh-air outlet (not via the anesthesia vaporizer).
After releasing the O_2 Flush push button it must return to it original position.





3.4 AIR/N_2O Mode Switch

The Air / N_2O Mode Switch is located below the rotary knobs for (AIR /N_2O). This offers a pre-selection of the gases AIR or N_2O. The respective dosage of the gases is effected via the regulation valve.

3.5 O_2- supply deficiency signal

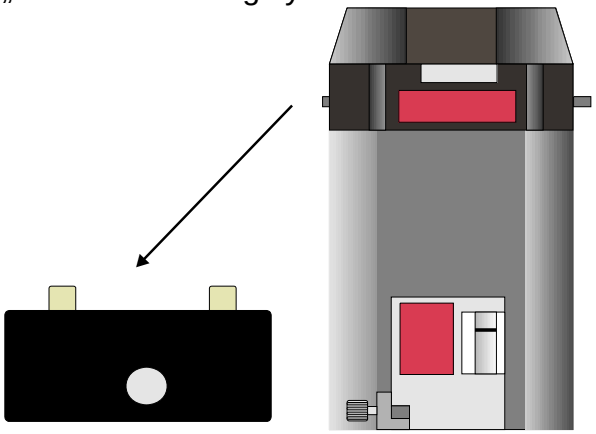
In the event of a pressure drop in the supply system (oxygen below 2.0 to 1.5 bar) an acoustic warning alarm is activated for a duration of at least 7 seconds. An interruption is not possible).

3.6 Nitrous Oxide Block

In the event of a further fall in presure of oxygen to about 1 bar,the ratio of N_2O is reduced proportionately to the oxygen supply. Should there be a total fallout of oxygen, the N_20 flow is set to zero. Release of N_2O is then closed.
The unit stand-by mode can be resumed only by setting the stipulated oxygen pressure of at least 2 bar at the network inlet.

3.7 Vaporizer

On request, the ARTEC inhalation anesthesia unit can be equipped with various vaporizer-systems. In the standard model, the vaporizerss come in use which are equipped with an „Interlock“ locking system to enable alternating operation of two vaporizers.



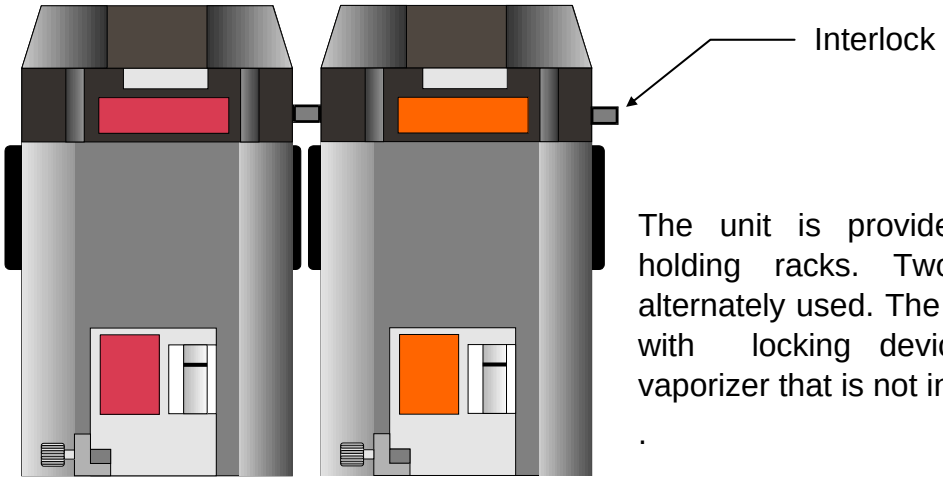
The anesthetic agent is mounted to the selected vaporizer rack by means of a click-in mechanism. The locking lever secures the vaporizer on the holding rack.

Please read the operating instructions of the respective model of vaporizer with which the ARTEC anesthesia unit is equipped.

Vaporizer holding-rack „single“

The unit is equipped with one vaporizer rack holder. Only one vaporizer can be put into operation.
The vaporizer holding rack is provided with automatic closing valves. The seal between the vaporizer and the holding rack takes on the function of a gasket ring placed on the valve.
Optionally, a side-rail possiblity for a second vaporizer can be provided besides the active vaporizer holding rack.

Vaporizer holding rack „two-fold“ Interlock locking system:



The unit is provided with two vaporizer holding racks. Two vaporizers can be alternately used. The vaporizers are provided with locking devices that disables the vaporizer that is not in operation

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3.8 Gas-cylinder Supply Component

When in the gas-cylinder operation mode, the gas is reduced from 200 or 50 bar to a working pressure of 5 bar. The cylinder pressure can be read on the pressure gauge and indicates the status of level fill of the gas bottles.

The feed of the gases to the actual unit is effected via the quick-fit couplings or the DIN threaded couplings which are unmistakeably coded according to type of gas being used.

Caution

When transporting, it is absolutely necessary to close the cylinder-valves.

4 Changeover mounting arm (optional)

As an option, the anesthesia system can be equipped with a changeover mounting arm. At the fresh gas outlet of this mounting arm a circuit system ISO 1 (Art.Nr. 11561006 / re-breathing system with CO_2 absorber) or all commercially available non re-breathing systems (e.g. Magill, Mapelson, Bain etc.) can be connected.

4.1 Top view

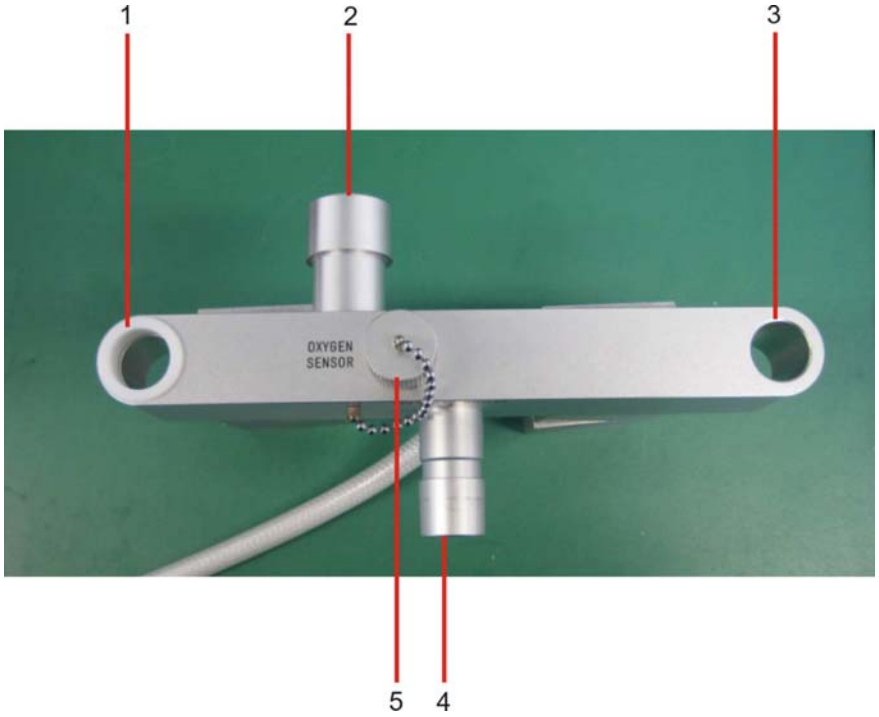

Fig. 1: Top view

1 Circuit system holder
2 Safety valve, connection for anesthetic gas aspiration Ø 28 mm
3 Fastening point anesthesia system
4 Fresh gas outlet
5 Adapter for O_2 sensor when using a non re-breathing system
(Must be sealed with the cap when using a circuit system /re-breathing system)

4.2 Front view

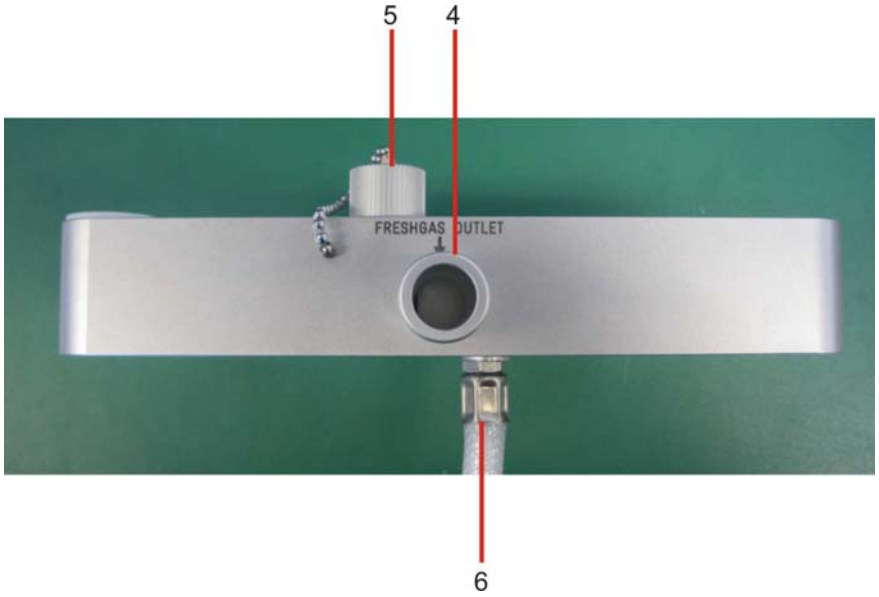

Fig. 2: Front view

4 Fresh gas outlet

5 Adapter for O_2 sensor when using a non re-breathing system (Must be sealed with the cap when using a circuit system / re-breathing system)

6 Fresh gas inlet coming from the gas mixing unit (GMU)

4.3 Rear view

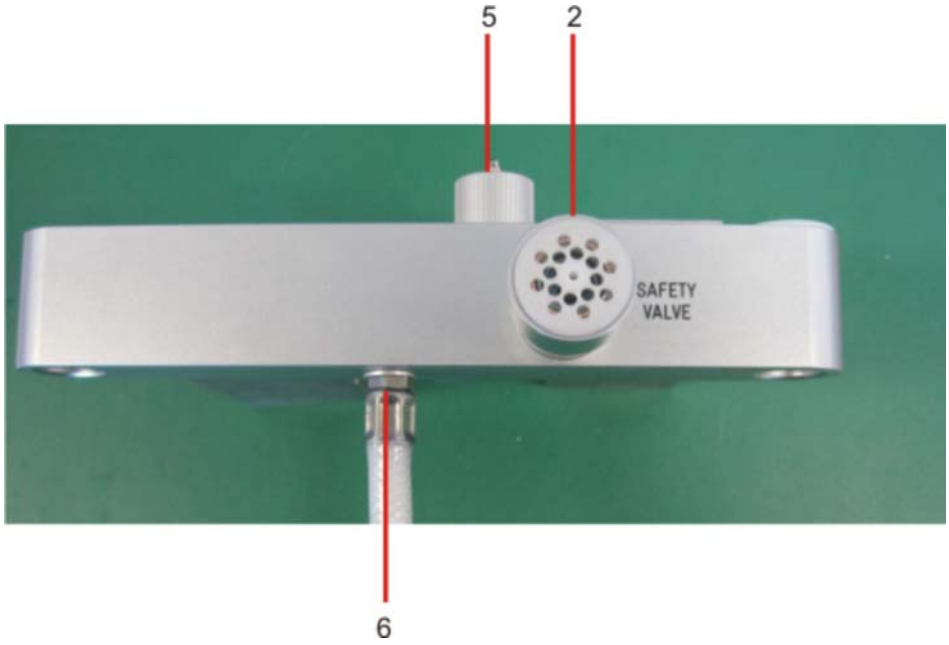

Fig. 3: Side view on the left

2 Safety valve, connection for anesthetic gas aspiration Ø 28 mm

5 Adapter for O_2 sensor when using a non re-breathing system
(Must be sealed with the cap when using a circuit system /
re-breathing system)

6 Fresh gas inlet coming from the gas mixing unit (GMU)

4.4 Connecting the changeover mounting arm

4.4.1 Connection to the circuit system (re-breathing system)

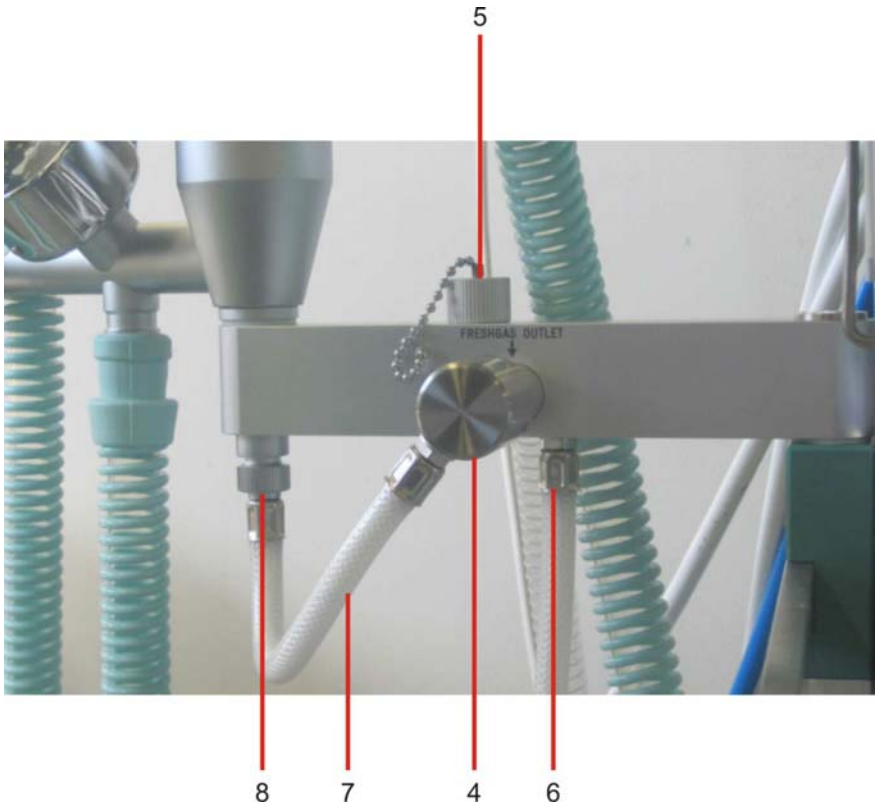

Fig. 4: Connection to the changeover mounting arm

4	Fresh gas outlet	6	Fresh gas inlet coming from the gas mixing unit (GMU)
5	Adapter for O_2 sensor when using a non re-breathing system (Must be sealed with the cap when using a circuit system / re-breathing system)	7	Connection hose for circuit system
		8	Fresh gas inlet of the circuit system

Proceed as follows to connect the mounting arm to the circuit system:

- Connect the fresh gas outlet of the GMU with compressed air hose to fresh gas inlet of the mounting arm (It. 6).
- Attach connection hose of the circuit system (It. 7) to fresh gas outlet of changeover mounting arm.(It. 4).

Caution

The adapter for O_2 sensor must be sealed with the cap when using a circuit system /re-breathing system.

4.4.2 Connection to a non re-breathing system

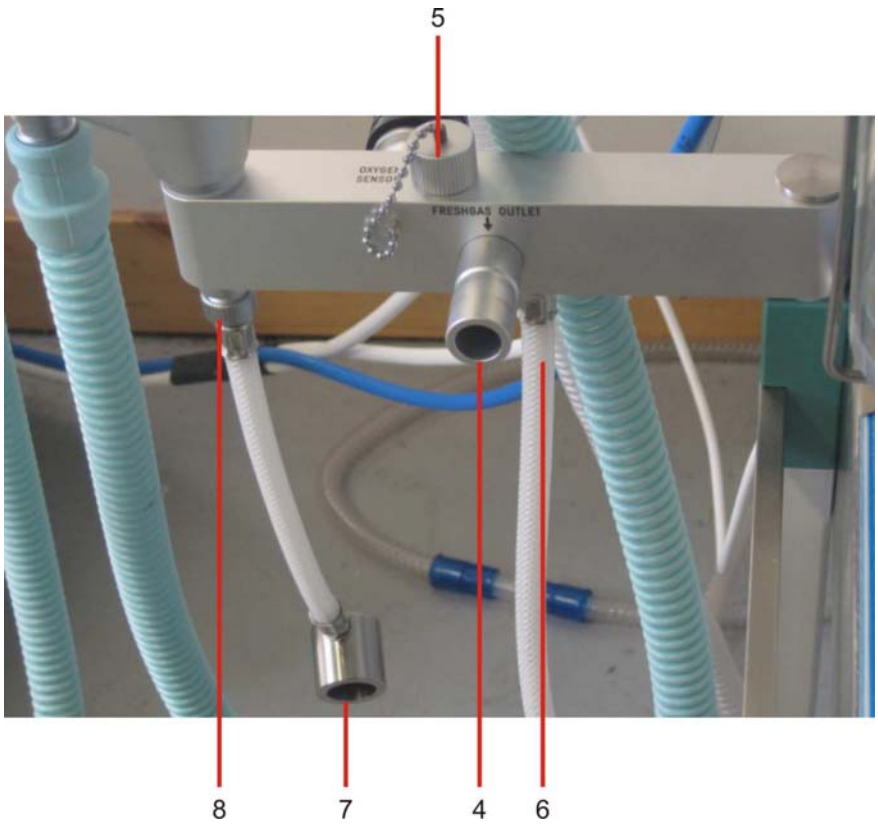

Fig. 5: Connection of the mounting arm to a non re-breathing system

4 Fresh gas outlet

5 Adapter for O_2 sensor when using a non re-breathing system (Must be sealed with the cap when using a circuit system / re-breathing system)

6 Fresh gas inlet coming from the gas mixing unit (GMU)

7 Connection hose for circuit system

8 Fresh gas inlet of the circuit system

Proceed as follows to connect the mounting arm to a commercially available non re-breathing system (e.g. Magill, Mapelson, Bain etc.) proceed as follows:

- Remove the connection hose for circuit system (It. 7) from the fresh gas outlet of the mounting arm (It. 4).
- Connect the non re-breathing system to the fresh gas outlet of the mounting arm (It. 4).

Caution

When using a non re-breathing system, an O_2 sensor must be connected to the adapter (It. 5).

Caution

When using a non re-breathing system, the APL valve of the circuit system fastened to the mounting device is not active. This is why it is advisable to use non re-breathing systems with integrated APL valve.

5 Testing Unit Functions

5.1 Dosage valves of the Gas Mix Unit

When closing the dosage valves make sure that the respective floating marker of the respective measuring tubes are re-set to zero. Otherwise, a leakage of the respective spindle will result that must be remedied by a service technician.

5.2 O_2-Flush

Before each operation of the ventilation unit check to see whether the O_2 bypass valve immediately and automatically closes after releasing the push-button.

Basic Setting:
Dosage valve (1) on measuring tube section is closed.

Conducting Test:
Briefly press the bypass button. On release of the push-button it immediately return to its initial position.

5.3 AIR / N_2O Mode Switch

Basic Setting:

- O_2 dosage valve closed
- N_2O dosage valve set to 3 litres per minute
- AIR dosage valve set to 3 litres per minute
- Mode Switch in „N_2O“ position
- Anesthesia aspiration unit connected
- O_2 monitor calibrated and in operating mode

Conducting Test:
The measuring tubes for N_2O must show 3 litres per minute flow, while the compressed measuring tube must indicate no flow. The O_2 monitor shows approx. 0% O_2 (after a brief waiting time).

When switching from N_2O to AIR – without changing dosage valve status – indication of floating marker of the N_2O measuring tube must return to zero, while, at the same time the display of the compressed-air measuring tube must indicate 3 litres per minute. The O_2 monitor shows 21% O_2 as comfirmation.

6 Gas Type Test and Testing Safety Devices

6.1 Testing Gas Type:

Check for proper connection of the anesthesia unit to the central gas supply system before operation of the unit.

Basic Setting:
Unit in operation mode
Anesthesia gas aspiration unit connected
O_2 monitor in standby mode and calibrated. Measuring at fresh gas outlet.

Conducting the test:

Oxygen (O_2):
Open the O_2 dosage spindle to approx. 1.5 to 2.0 litres per minute.

The O_2 monitor must display approx. 98 to 99 O_2.

Nitrous Oxide (N_2O):
When using an Artec with N_2O, close the Air dosage valve and open the N_2O valve. Check the N_2O concentration with an external anesthesia gas module.

Compressed air (AIR)
Open the AIR dosage spindle to approx. 1.5 to 2.0 litres per minute

The O_2 monitor must display approx. 21% O_2

Danger

In the event of any deviance, the unit must undergo a service inspection!

6.2 Testing the O_2 deficiency signal / nitrous oxide block:

Basic Setting:

Unit in operation mode
Anesthesia aspirator device connected
All dosage valve spindles opened to 3 litres per minute
AIR / N_2O Mode Switch in N_2O position

Conducting test:

Remove angle plug for O_2 from circuit
The oxygen flow must continuously decrease
At apprix. 2.0 to 1.5 bar circuit pressure the **O_2 deficiency signal** is activated

When pressure further decreases to approx. 1 bar, the **nitrous oxide block** is activated and the N_2O flow sinks parallel to the oxygen flow, until for a fully empty system both volumen flows fall to zero.
By re-connecting the O_2 angle plug, the oxygen supply is re-established.
Interruption of the N_2O feed line. The N_2O flow sinks to zero.

Danger

In the event of deviations of the description above, please inform customer service.

6.3 Testing the Vaporizer / Vaporizer holding rack

The anesthesia agent vaporizer is to be check for its proper function before using the unit.

Basic Setting:
Unit set in operation mode
Anesthesia agent vaporizer filled and ready for operation

Conducting the test:

Vaporizer:
Check adjusting and locking device for proper functioning
Check level status display for damage
Check adapter for safety support for damage
Check vaporizer locking lever

Condition of Vaporizer:

Check sealing valve for leakage
Inspect sealing gasket for exterior damage

7 Cleaning and Care of Anesthesia Unit

The anesthesia unit is to undergo a thorough cleaning at appropriate intervals; whereby servicing measures must also be conducted that will prolong the service life of the machine.

After removing the vaporizer, the unit can be wiped clean using a common detergent agent. It is highly recommended to follow this up by using a dry cloth to remove any moisture and thus limiting any danger of corrosion.
Special attention should be given to the O-rings located at the vaporizer holding rack. These are to be carefully removed, cleaned and replaced in a dry condition.
Should these rings show damage of any type, they are to be replaced by new O-rings.

For the changeover mounting arm no maintenance work is required. Parts of the changeover mounting arm should only be replaced or repaired by the customer service of F. STEPHAN GMBH.

8 Troubleshooting

8.1 ARTEC

Error	Possible Cause(s)	Remedy
Floating marker of the measuring tubes do not return to zero	Measuring tube is dirty Dosage valve leakage	Clean measuring tube Loosen rotary knob and re-set (Service)
When using Mode Switch AIR/N_2O switch, the selected gas is not activated (indicated via O_2 monitor)	Mode switch valve is not properly sealed.	Replace mode switch valve (customer service)
Oxygen concentration too high	Leakage in oxygen dosage valve Flush Valve does not close properly	Loosen rotary knob and re-set (customer service) Replacement of Flush Valve by customer service
O2 deficiency signal is constantly activated	Supply pressure too low Valve is defect	Set pressure reducer of the bottle supply higher Have customer serve replace valve

8.2 Changeover mounting arm (if available)

Störung	Ursache	Mögliche Fehlerbeseitigung
When using the circuit system: No or not enough fresh gas supplied to the circuit system	Connection hose of the circuit system is not connected to the fresh gas outlet of the mounting arm	Attach the connection hose of the circuit system to the fresh gas outlet of the mounting arm
	Setting for fresh gas flow is too low at the gas mixing unit (GME)	Adjust correct setting for fresh gas flow at the GMU
	Supply hoses at the changeover mounting arm are not correctly connected or not properly fastened	Check the connection of the supply hoses at the changeover mounting arm; if necessary, connect and fasten correctly
	Wrong setting of APL valve	Check setting of APL valve
When using a non re-breathing system: No or not enough fresh gas supplied to the non re-breathing system	Connection hose of the non re-breathing system is not connected to the fresh gas outlet of the mounting arm	Attach the connection hose of the re-breathing system to the fresh gas outlet of the mounting arm
	Frischgasstrom an der Gasmischeinheit (GME) ist zu niedrig eingestellt	Adjust correct setting for fresh gas flow at the GMU en
	Supply hoses at the changeover mounting arm are not correctly connected or not properly fastened	Check the connection of the supply hoses at the changeover mounting arm; if necessary, connect and fasten correctly
	Wrong setting of APL valve	Check setting of APL valve

9 Technical Data

Inhalation Anesthesia Unit MPG-Class 2b, Model Registration Number: 11 / M-01491
Typ: B Protection Class: 1
U: 230 V AC
P: 80 VA (with ventilator)

Dimensions (with Ventilator ABVA)
Width: 500 mm
Height: 1350 mm
Depth: 630 mm

Dimensions (without Ventilator ABVA)
Width: 500 mm
Height: 1240 mm
Depth: 630 mm

Connections (threaded) for Gas Types:
O_2: M 12 x 1
AIR: M 20 x 1.5
N_2O: M 14 x 1
Fresh Gas: M 16 x 1.5
Circuit pressure 5 bar +/- 0.5 bar

Measuring range for measuring hoses:
O_2 (fine) : 0 to 2 litres per minute
(roughly) : 2 to 15 litres per minute

AIR : 0 to 15 litres per minute
N_2O : 0 to 15 litres per minute

Precision of Measuring tubes:
+/- 10% of the respective end scale value. For integrated micro measuring range +/- 10% of the measuring endscale value (under standard conditions 20ºC and 1.013 bar)

O_2 deficiency signal:
Trigger pressure: 2.8 bar
Duration of acoustic warning signal 7 seconds

N_2O Block:
Trigger pressure: 2.0 bar

10 Maintenance and Servicing

10.1 Artec

Medico-technical products and required to undergo at regular intervals inspection and servicing in compliance with MedGV (Medical Equipment Regulations).

Such inspections and servicing are to be carried out by authorized personnel only (Service Staff) of the Supplier.

Periodic Maintenance is genenally semi-yearly.
Safety Technical Inspections

Recommended Scope:

1. Visual check of necessary identification markings and Exterior detected damage
2. Check for completeness of Unit
3. Check proper functioning and alarm functioning
4. Measure earthing resistance, replacement unit ground contact and the insulation resistance in comliance with VDE 0751 Part 1/12.84

The Maintenance Agreement ensures the best guarantee, and provides semi-annual inspections with automatic replacement of parts subject to wear.

Should maintenance and servicing of the unit be carried out by unqualified and unauthorized persons, the Manufacturer cannot be held reliable for the safe and proper functioning of the unit.

10.2 Changeover mounting arm (if available)

For the changeover mounting arm no maintenance work is required. Parts of the changeover mounting arm should only be replaced or repaired by the customer service of F. STEPHAN GMBH.

F. Stephan GmbH
- Medizintechnik -
Kirchstrasse 19
56412 Gackenbach

☎ (+)49 (6439) 9125 – 0
🖹 (+)49 (6439) 9125 – 111
✉ info@stephan-gmbh.com
💻 www.stephan-gmbh.com